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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,382	09/09/2004	Jian Luo	MGC020325	6441

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

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01/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,382	LUO ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/2009 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The rejection of claims 9-10 under 35 U.S.C. 103(a) as being unpatentable over Weintraube et al (Atherosclerosis, 1998) is maintained.

Applicant argues that Weintraube et al fails to teach the method for reduction of plasma glucose concentrations in diseases, disorders or conditions in human or non-human mammals as specified in claim 9. Weintraube et al further fails to teach the use of a composition consisting of two agents. Weintraube et al teaches away from the claimed invention as it teaches administering gemfibrozil to type IV HLP patients.

Applicant's arguments have been fully considered but are not found persuasive. Claim 9 encompasses administering a pharmaceutical composition consisting of, as active agent, (1) a glucose-lowering agent metformin in one of its pharmaceutically acceptable forms, and (2) a lipid-improving agent selected from non-glucose-lowering fibrates to a human or non-human mammal. The disclosure of Weintraube et al renders obvious all active steps of the claimed method.

It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. Gemfibrozil and metformin are taught by Weintraube to be used for the very same purpose, i.e. for the clearance of PPLp. Weintraube teaches that "gemfibrozil... and metformin were shown to be beneficial in the clearance of PPLp…" (see abstract; conclusion). Weintraube teaches that both compounds may be used for the clearance of PPLp in patients suffering from atherogenic conditions. As the two compounds are used for the very same purpose (i.e. clearance of PPLp in patients suffering from atherogenic conditions), their combination is obvious, and it would be obvious to co-administer gemfibrozil and metformin to patients to treat atherogenic conditions.

The Examiner agrees with Applicant that the purpose of combining and administering these agents is not to reduce plasma glucose concentrations in the diseases, disorders or conditions listed in instant claim 9. However, there is no language in instant claim 9 that the human or non-human mammal is in need of a reduction in plasma glucose concentration. As a composition cannot be separate from its properties, the administration of the two agents (for the purpose of treating

atherogenic conditions) must inherently be reducing plasma glucose concentrations in the same patients.

> "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997)." MPEP § 2111.02.

> "In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.)." Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)."

> "In a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. Thus the claim is properly interpreted to mean that the vitamin preparation must be administered to a human with a recognized need to treat or prevent pernicious anemia.)" In re Cruciferous Sprout Litig., 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002).

In the present case, the Examiner recommends replacing "administration of a pharmaceutical composition to said human or said non-human mammals" in instant claim 9 with "administration of a pharmaceutical composition to a human or non-human mammal in need thereof". Such language indicates that the agents must be administered to a human or non-human mammal in need of reduction of plasma glucose concentration.

New Grounds of Rejection

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites “a method for reduction of plasma glucose concentrations in diseases, disorders or conditions in human or non-human mammals”. This language is cumbersome and renders the claim indefinite. It is unclear what the relationship between the plasma glucose concentration and the diseases, disorders or conditions is and what is actually being treated by the claimed method. Is this a method of treating the disclosed diseases, disorders or conditions, a method of reducing plasma glucose concentration, or both? In one interpretation, this is a method of reducing plasma glucose concentrations only, and the disclosed diseases, disorders or conditions are merely referenced as a benchmark for the reduction of plasma concentration. They could be used as a benchmark as follows: the glucose concentrations to be reduced are the same glucose concentrations observed in patients having the disclosed diseases, disorders or conditions. In this interpretation, the diseases, disorders, or conditions themselves are not being treated, nor does the patient have the diseases, disorders, or conditions, but "reduction of plasma glucose concentrations in diseases, disorders, or conditions" indicates that glucose concentrations observed in patients having these

diseases, disorders or conditions are the same glucose concentrations that are reduced by the method. Again, in this interpretation, the diseases, disorders or conditions are not themselves being treated, nor does the patient have these diseases, disorders, or conditions. This is a reasonable interpretation of "reduction of plasma glucose concentrations in diseases, disorders or conditions in human or non-human mammals". Alternatively, the claim could be interpreted as treating the diseases, disorders or conditions themselves. The recitation of "reduction of plasma glucose concentrations" is an explanation of the mechanism by which the agents treat the diseases, disorders or conditions. This is an equally reasonable interpretation of "reduction of plasma glucose concentrations in diseases, disorders or conditions in human or non-human mammals". Due to these multiple interpretations of the claim, it is unclear what is being treated/accomplished by the claimed method. The skilled practitioner would not know what constitutes infringement on the claimed invention.

The dependent claims do not clarify this ambiguity and are indefinite for the same reason.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weintraub et al (Atherosclerosis, 1998; document already in record). Weintraub et al discloses that gemfibrozil and metformin are known to be beneficial for the clearance of PPLp in patients suffering from atherogenic conditions (see abstract; Discussion). Gemfibrozil was administered at 1200 mg/day and metformin was administered separately at 1700 mg/day to a human or non-human mammal (see Table 1). Weintraub et al fails to disclose administration of a pharmaceutical composition consisting of (1) metformin and (2) gemfibrozil.

It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. As gemfibrozil and metformin are used for the very same purpose, i.e. for the clearance of PPLp in patients suffering from atherogenic conditions, it would be obvious to combine these two agent (such as in an admixture), to treat patients suffering from atherogenic conditions. There is no language in instant claim 9 that the human or non-human is in need of a reduction in plasma glucose concentration. As a composition cannot be separate from its properties, the administration of the two agents (for the purpose of treating atherogenic

conditions) must inherently be reducing plasma glucose concentrations in the same patients. The Examiner recommends replacing "administration of a pharmaceutical composition to said human or said non-human mammals" in instant claim 9 with "administration of a pharmaceutical composition to a human or non-human mammal in need thereof". Such language indicates that the agents must be administered to a human or non-human mammal in need of reduction of plasma glucose concentration.

It would be further obvious to find Applicant's metformin to gemfibrozil weight ratio range of 1:0.5 to 1:2, through routine experimentation, to afford a more effective dosage form for clearing PPLp in hypertriglyceridemic patients. Weintraub et al discloses administering 1700 mg/day of metformin and 1200 mg/day of gemfibrozil. If these two dosage forms were combined together, the metformin to gemfibrozil weight ratio would be 1700:1200, or 1:0.71. This weight ratio is encompassed by the instantly claimed ranges, and thus it would be obvious to find these ranges through routine experimentation. See MPEP § 2144.05, II.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

January 12, 2010